REMARKS

By this Amendment, claims 1, 3, 4, 5, 7, 9, 10, 12 and 14 are amended, claims 8, 11, 13, 16, and 17 are cancelled, and new claims 18-32 are added. Claims 1-7, 9, 10, 12, 14, 15, and 18-32 are pending in the application.

Support for the amendments to claims 1, 3, 4, 5, 7, 9, 10, 12 and 14, which are now directed to telmisartan, are found in the originally filed claims, examples (¶¶ [0122]-[0129]), and throughout the Specification. Support for "total effective daily orally administered dose ... selected from the range of about 0.05 to 100 mg/kg body weight" specified in claim 14, as amended, is found in paragraph [0068]. Support for "elevated serum concentrations of LDL-cholesterol" specified in claims 4 and 7, as amended, is found at page 19, paragraph [0065].

Support for the new claims 18-32, and directed to irbesartan, or analogs thereof, are found in the originally filed claims, and ¶¶ [0026], [0065], [0068], [0070], [0072-0074], [0087], [0112], [0118], [0123], and [0124] and throughout the Specification. No new matter is added by these amendments.

Reconsideration of the application is respectfully requested in view of the above amendments and the following remarks. For the Examiner's convenience, Applicant's remarks are presented in the order in which they were raised in the Office Action.

A. Cancellation and amendment of claims

Applicants have cancelled certain claims and amended certain other claims solely to expedite prosecution of the current application. Amendment and cancellation of certain claims are not to be construed as acquiescence to the grounds for their rejection in the Office Action unless expressly acknowledged in this response. Amendment and cancellation of certain claims are not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Applicants reserve the right to pursue the amended and cancelled claims in a future continuation or divisional application.

B. Obviousness-type Double Patenting Rejection

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 58-87 of copending Application No. 10/801,437.

Applicants will file a terminal disclaimer in the appropriate case – the present application or U.S. Ser. No. 10/801,437 – to disclaim any term beyond the term of the earlier expiring patent in order to overcome this ground for rejection, after the conflicting claims are found allowable.

C. Claims Rejections Under 35 U.S.C. §112, first paragraph

Claims 1-15 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for treating type 2-diabetes, metabolic syndrome and inflammation caused by osteoarthritis with telmisartan, does not reasonably provide enablement for treating all inflammatory or metabolic disorders or prophylactically preventing an inflammatory or metabolic disorder by administering all compounds sufficient to at least partially activate peroxisome proliferators activated receptors (PPARs) and at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptors.

Claim 1 is amended to specify treating or prophylactically preventing an inflammatory or metabolic disorder in a mammal by administering "telmisartan, or an analog thereof, sufficient to (a) at least partially activate peroxisome proliferator activated receptors (PPARs) and (b) at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptors." Amended claim 1 now specifies "telmisartan" and analogs thereof which the Examiner has found to be enabling. (Office Action, page 4). Recitation of the general term "a compound" which had been objected to in the Office Action has been removed.

New claim 18 specifies the use of telmisartan "administered in a therapeutically effective amount sufficient to prophylactically prevent, slow, delay or treat at least one metabolic disorder or disease selected from the group consisting of type 2 diabetes mellitus, metabolic syndrome, and inflammation caused by osteoarthritis" which the Examiner considered enabled. (page 4 of the Office Action). Claims 1-7, 9, 10, 12, 14, 15, and 18 depend from claim 1. Applicants respectfully request withdrawal of this ground for rejection.

New claims 19-32 specify use of irbesartan as the therapeutic compound. Paragraphs [0070], [0072-0074] of the Specification discloses the novel use of irbesartan "to treat or prevent insulin resistance, the metabolic syndrome and type 2 diabetes (i.e. lower hyperinsulinemia and/or hyperglycemia), lower triglycerides, and elevate HDL-cholesterol." (¶ [0070]). Paragraphs [0026], [0065], [0068], [0070], [0072-0074], [0087], [0112], [0118], [0123], and [0124] disclose suitable properties of irbesartan.

Applicants also note that publications subsequent to the filing of this application confirm the results predicted in the Specification. Applicants enclose an article by Bramlage P, Pittrow D, Kirch W. entitled "The effect of irbesartan in reducing cardiovascular risk in hypertensive type 2 diabetic patients: an observational study in 16,600 patients in primary care." in *Curr. Med. Res. Opin.* 20:1625-1631 (2004). (*see attached*). Bramlage *et al.* show the lowering of LDL cholesterol and triglycerides resulting from the administration of irbesartan. New claims 31 and 32 are directed to these particular effects of irbesartan.

Applicants submit that the Specification is enabled for the use of telmisartan and irbesartan in the prevention and treatment of the metabolic disorders and diseases specified in the claims and respectfully request withdrawal of this ground for rejection.

D. Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 11 and 13 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 13 are cancelled. Therefore, this ground for rejection is moot.

E. Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1, 3-7, 13 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by O'Donnell et al.

O'Donnell discloses the use of irbesartan, not telmisartan.

(i) Independent claim 1 and claims 3-7 which depend therefrom are amended to specify that the compound is telmisartan. Claim 14 is amended to depend from claim 9, which depends

from claim 1, and is directed to telmisartan. Since O'Donnell refers only to irbesartan and does not disclose telmisartan, O'Donnell does not disclose each and every element of claims 1 and 3-7, as amended.

Claim 13 is cancelled. Therefore, grounds for rejection of this claim is moot.

New claim 18 specifies telmisartan.

Therefore Applicants respectfully submit that claims 1-7, 9, 10, 12, 14, 15, and 18, which are directed to telmisartan (and not irbesartan) are not anticipated by O'Donnell.

(ii) New claims 19-32 are directed to irbesartan

Claims 19, 24 and 30 specify that "irbesartan is administered in a therapeutically effective amount sufficient to prophylactically prevent, slow, or delay at least one metabolic disorder or disease" related to diabetes. Claims 19, 24 and 30 do not specify the use of irbesartan in the treatment of animals suffering from diabetes. Claim 30 specifies the use of irbesartan in the treatment of "prediabetes."

O'Donnell is cited for disclosing the lowering of blood pressure and the amelioration of renal injury in rats suffering from non-insulin-dependent diabetes mellitus. (*see* Abstract.) Thus, O'Donnell discloses the use of irbesartan in the "treatment" of animals already suffering from non-insulin-dependent diabetes mellitus. Since claims 19, 24 and 30, and claims depending therefrom do not specify using irbesartan for the treatment of animals suffering from non-insulin-dependent diabetes mellitus, as disclosed by O'Donnell, and O'Donnell does not teach or suggest the use of irbesartan to "prophylactically prevent, slow, or delay" diabetes or treat "prediabetes," O'Donnell fails to anticipate claims 19-32. O'Donnell does not teach or suggest the other uses of irbesartan to "prophylactically prevent, slow, delay or treat" non-diabetes-related diseases and disorders specified in the instant claims, O'Donnell fails to teach each and every element of claims 19-32.

Applicants submit that new claims 19-32 are not anticipated by O'Donnell.

Applicants respectfully request withdrawal of this ground for rejection.

F. Claim Rejections Under 35 U.S.C. § 103(a)

Claims 8-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Naka et al. (U.S. Pat. No. 6,100,252).

Independent claim 8 is cancelled. Its rejection over Naka is moot.

Claims 9 and 10 which depended from claim 8, have been amended to depend from claim 1. Naka does not teach or suggest telmisartan, specified in claim 1, as amended. The Examiner has not pointed to any teaching that would motivate a skilled artisan to replace the heterocyclic compounds of Naka with telmisartan for treating inflammatory or metabolic disorders. Claims 2-7, 9, 10, 12, 15, and 18 depend from independent claim 1.

Claims 19-32 are directed to the use of irbesartan. The Examiner has not pointed to any teaching that would motivate a skilled artisan to replace the heterocyclic compounds of Naka with irbesartan for treating inflammatory or metabolic disorders.

Therefore, Applicants respectfully submit that the instant pending claims are not obvious over Naka under 35 U.S.C. §103(a).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Applicants request entry of these amendments and request the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 421842000400. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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